IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust Litigation	Case No. 1:15-cv-07488-CM (RL)
THIS DOCUMENT RELATES TO: All Direct Purchaser Actions	FILED UNDER SEAL

MEMORANDUM OF LAW IN SUPPORT OF FOREST'S MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF JANET K. DELEON

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND RULES

I. INTRODUCTION

The purported expert report of Janet K. DeLeon is nothing more than a summary of documents and testimony and mere speculation by Ms. DeLeon that because the launch of some generic Namenda IR products in 2015 occurred without manufacturing, equipment or supply impediments, there would have been no impediments to the same suppliers launching at any time between June 2012 and July 2015. Ms. DeLeon relies solely on her review of documents and testimony regarding the product launches in 2015, and her experience at two small pharmaceutical companies and two small consulting firms to speculate that the Generics and Forest could have launched their generic Namenda IR products as early as June 2012. Ms. DeLeon did not review or rely on any documents or testimony discussing the Generics' or Forest's manufacturing capabilities in 2012, 2013, or 2014, their ability to obtain a steady supply of memantine API in 2012, 2013, or 2014, or their available production capacity in 2012, 2013, or 2014, such that they would have been able to produce generic Namenda IR any earlier than 2015. And Ms. DeLeon's reliance only on her experience with much smaller drug products at much smaller drug companies does not allow for such "expert" speculation here, especially when her conclusion is not based on any actual documents or testimony regarding the capabilities of generic companies to manufacture generic Namenda IR in 2012. Her unreliable and speculative opinion will confuse and mislead the jury and should be excluded.

II. BACKGROUND

Ms. DeLeon submitted an opening expert report and a supplemental expert report opining on: (1) whether anything would have prevented Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Lupin Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., and Sun Pharmaceutical Industries, Inc. (collectively "Generics") "from launching their respective generic Namenda IR tablet products any time between June 2012 and July 2015;" and (2)

"whether, upon the launch of a generic Namenda IR by any of the Generics, anything prevented Defendants from launching an authorized generic Namenda IR." Decl. of Michael E. Hamburger, Ex. 10 (Expert Report of Janet K. DeLeon, dated Sept. 15, 2017) ("DeLeon Rep.") ¶¶ 4–6; *see also* Hamburger Decl., Ex. 11 (Expert Suppl. Report of Janet K. DeLeon, dated Oct. 23, 2017) ("DeLeon Suppl. Rep.").

In her reports, Ms. DeLeon summarizes documents and witness testimony discussing the development of generic Namenda products in 2015, and then concludes that because the Generics and Forest were able to launch their generic Namenda products in 2015, nothing would have prevented the Generics or Forest from launching generic Namenda IR as early as June 2012. Hamburger Decl., Ex. 10 (DeLeon Rep.) ¶¶ 123, 127, 129, 131, 133, 135, 137.

[redacted] Hamburger Decl., Ex. 25 (DeLeon Dep.) at 77:6-14. [redacted] Hamburger Decl., Ex. 28 (Gupta (Amneal) Dep.) at 12:4-7, 165:7-167:5, 201:24-203:12; Hamburger Decl., Ex. 29 (Nadkarni (Sun) Dep.) at 216:2. She also reviewed the record documents provided to her by Plaintiffs' counsel relevant to the 2015 launch of the Generics' Namenda IR products. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 73:19-74:17. Ms. DeLeon did not cite to any academic literature, but did review and rely on some public sources, including the FDA website, Amneal's 2017 website, and the 2015 Form 10-K or Annual

[redacted] Dr. Reddy's, Lupin, [redacted] and Sun. [redacted]

In concluding that Forest could have launched an authorized generic Namenda product earlier than July 2015, Ms. DeLeon looked at the testimony of only one Forest witness, June K. Bray, when drafting her original report. Hamburger Decl., Ex. 10 (DeLeon Rep.) ¶¶ 64-66; 71-73; 137-138. Her report did not include any relevant testimony from Forest's business executives who testified during the NYAG case about the possibility of the launch of a Namenda authorized generic prior to 2014. *See* Hamburger Decl., Ex. 25 (DeLeon Dep.) at 248:12-22. While Ms. DeLeon reviewed the 2017 depositions of Julie Snyder and David Solomon when drafting her October 23, 2017 Supplemental Report (Hamburger Decl., Ex. 11 (DeLeon Supp. Rep.) Ex. A), she did not cite to Mr. Solomon's testimony regarding the Namenda authorized generic and admitted that she didn't have enough time to thoroughly review the depositions and exhibits before submitting the report. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 253:2-22.

III. ARGUMENT

A. Ms. DeLeon's Opinions Are Not Based On Sufficient Facts Or Data

During her deposition, Ms. DeLeon admitted that she did not review any documents or deposition testimony that support her conclusion that Generics had the manufacturing capacity, equipment availability or memantine supply in 2012 such that they could have launched generic Namenda IR in 2012. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 89:24-91:23 ("Q. So when you say they had their ducks in a row in 2015, you didn't see or look at any documents or evidence showing their ducks in a row in 2012; is that fair? A. Yeah, I couldn't have looked at them because they weren't available"), 132:14-133:15 (same), 143:14-22, 145:10-149:3, 162:14-164:18, 167:15-18, 170:1-174:24, 174:25-175:12, 182:10-12; 183:11-22 ("Q. You did not look at a Generics' manufacturing capabilities, their production capacity or their availability of supply

for generic memantine in 2012, when forming your conclusions here? A. Yeah, it didn't apply because the reality was the 2015 launch, so . . . ."), 184:4-184:22 (testifying that she did not review anything from 2012 in terms of Generics manufacturing capabilities), 189:7-13; 200:22-201:9; 263:9-18 (agreeing that no witnesses testified that memantine API was readily available in 2012); 266:19-24; 272:23-273:1.

Ms. DeLeon merely assumes that because the Generics had "their ducks in a row" in 2015, they would necessarily be able to launch in 2012 (or any other time). *Id.* at 89:24-91:11 (explaining that her conclusions would not change if she was asked whether the generics could launch in 2010 because her conclusions are based on what happened in 2015). However, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (upholding district court's exclusion of expert opinion where there was "too great an analytical gap between the data and the opinion proffered."); *Amorgianos v. Amtrak*, 303 F.3d 256, 266, 270 (2d Cir. 2002) ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.").

Despite acknowledging that "a million things" could go wrong that would delay a generic manufacturer's launch of a product, Ms. DeLeon did not look at anything in 2012, 2013, or 2014 to determine if there were any such issues present at those times. Hamburger Decl., Ex. 10 (DeLeon Rep.) ¶ 38; Hamburger Decl., Ex. 25 (DeLeon Dep.) at 130:12-131:22 ("There's a million things that could go wrong"); 142:24-143:12 (same); 180:15-17 (same); 236:12-16 (same). When confronted with realities that may have affected the Generics' launch in 2012

such as a closed manufacturing plant or a generic company that was half the size in 2012 than it was in 2015, Ms. DeLeon consistently replied that those other factors "did not apply" or "it was not within the scope" of her report, with little other explanation as to why it was not relevant to consider those factors when assessing whether "anything" prevented the Generics from launching earlier. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 167:4-13 (testifying that information about a company's overall production capacity in 2012 "would not apply"); 167:15-24 (agreeing that she did not consider Dr. Reddy's manufacturing capabilities in 2012 because "it wasn't part of the scope for this") 170:15-23; 171:3-5; 174:14-24; 175:4-12; 183:11-22 ("Q. You did not look at a Generics' manufacturing capabilities, their production capacity or their availability of supply for generic memantine in 2012, when forming your conclusions here? A. Yeah, it didn't apply because the reality was the 2015 launch, so . . ."); 189:8-12 (testifying she did not consider that Sun had twice the number of operational facilities in 2015 than it did in 2012 because "It didn't apply."); 193:3-12; 197:14-21 ("Q. And there was no testimony as to whether or not he would have or Sun would have encountered any problems in 2012, 2013, or 2014? A. Yes, as discussed earlier, it didn't apply. The questions were not focused towards problems that they would have had in 2012. They were focused on did you have problems in 2015."); 205:1-6.

Ms. DeLeon attempts to excuse the lack of evidentiary support cited in her report by noting that documents relevant to 2012 were "not available" or were not produced by the Generics. *Id.* at 90:17-25; 91:2-11; 184:13-22 ("Q. Is your answer no to that question, you did not review anything from 2012 in terms of the Generics' manufacturing capabilities? A. It wasn't provided and I did not seek it out on my own."). However, that documents and deposition testimony evidencing the Generics' manufacturing capabilities in 2012 were not

subpoenaed or elicited by Plaintiffs' counsel, does not warrant the admission of Ms. DeLeon's speculative conclusions. *Davis v. Carroll*, 937 F. Supp. 2d 390, 418 (S.D.N.Y. 2013) ("Where an appraisal or other expert testimony rests on inadequate factual foundations, problematic assumptions, or a misleadingly partial selection of relevant facts, it must be excluded under Rule 702.").

Notwithstanding this, Ms. DeLeon admits that she did not ask counsel to provide any documents that could have filled the evidentiary gaps in her report. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 74:19-75:7. Nor did she make any effort to search even for public documents from 2012, such as annual reports, that would potentially show the Generics' manufacturing capabilities, despite citing to similar 2015 documents to bolster her conclusions. *Compare* Hamburger Decl., Ex. 10 (DeLeon Rep.) nn.139-141, 147-148, 154-155 (citing to Lupin's 2015 annual report to show that Lupin has manufacturing facilities in the US, Europe, Canada, Mexico, South Africa, Japan, and India, is the sixth-largest generic pharmaceutical company in the US with annual sales of over $2 billion, has significant experience launching generic drugs, had 77 FDA-approved products on the US market, and 210 ANDAs in the pipeline awaiting FDA approval), 164-167, 174-175 *with* Hamburger Decl., Ex. 25 (DeLeon Dep.) at 182:10-12 (testifying that she did not look at Generics 2012 10-Ks or annual reports). By blindly assigning what happened in 2015 to 2012, Ms. DeLeon fails to account for the variable that over three years, the Generics expanded, refined their launch planning protocols, improved their manufacturing equipment, increased their capacity, and may have been better prepared to launch in 2015 than they were in 2012, 2013, or 2014.

Ms. DeLeon failed to even consider the portions of the evidentiary record that did apply to her analysis. Despite being tasked with considering whether "anything prevented Defendants

from launching an authorized generic Namenda IR," Ms. DeLeon testified that she did not consider the 2014 testimony of Forest's CEO, Brent Saunders, stating that [redacted]. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 245:7-248:11 (dismissing the testimony as a preference that could have changed). She similarly dismissed the 2014 testimony of David Solomon (a senior executive of Forest at the time) [redacted] *Id.* at 254:1-255:17. Ms. DeLeon's conclusion that nothing would have prevented Forest from launching an authorized generic in 2012 is inconsistent with the evidence presented in this case and should be excluded. *Davidov v. Louisville Ladder Grp., LLC*, 2005 U.S. Dist. LEXIS 3117, at *3-4 (S.D.N.Y. Mar. 1, 2005) (excluding expert testimony that only served to support a conclusion which is in conflict with the factual evidence); *see also Weisfelner v. Blavatnik (In re Lyondell Chem. Co.)*, 558 B.R. 661, 669 (Bankr. S.D.N.Y. 2016) ("To the extent the reports contain additional factual narratives and cherry-picking of evidence, those sections must also be excluded."); *Davis*, 937 F. Supp. 2d at 418-20 (excluding expert testimony in part due to expert's failure to "reckon with any of the record evidence" when reaching his conclusion).

B. Ms. DeLeon Relied On Factual Assumptions Contradicted By The Record

Ms. DeLeon explains in her report that she was told by Plaintiffs' counsel to assume that the Generics had final FDA approval for their ANDAs, such that there were no regulatory obstacles to launch in June 2012. Hamburger Decl., Ex. 10 DeLeon Rep. ¶¶ 7-8. However, this assumption is not supported by the record, and further undermines the reliability of Ms. DeLeon's opinions. *Davis*, 937 F. Supp. 2d at 418-20 (holding that an expert report must be

stricken where the expert relied on factual assumptions unsupported or contradicted by the record).

Ms. DeLeon testified that while she understood that not all of the Generics had final approval by June 2012, "we're in a but for world, not in reality, that could have all changed if they were wanting to launch by 2012 instead." Hamburger Decl., Ex. 25 (DeLeon Dep.) at 136:9-14. That type of speculation is not admissible: [redacted], Amneal, and Lupin all [redacted], and Plaintiffs' counsel instructed Ms. DeLeon to not examine whether they could have received final approval earlier. Hamburger Decl., Ex. 10 (DeLeon Rep.) ¶ 8; Hamburger Decl., [redacted]); Hamburger Decl., Ex. 28 (Gupta (Amneal) Dep.) at 61:13-62:15; Hamburger Decl., Ex. 39 (LPI-NMDA-00004618).

The assumption that there were no regulatory obstacles was so far reaching that Ms. DeLeon did not bother to confirm whether the manufacturing facilities the Generics used to manufacture their generic Namenda IR products were open and running from 2012 to 2015. Instead, she merely assumed that they would be. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 142:2-144:8. Even Ms. DeLeon concedes that "a lot of things can happen" between tentative and final approval, which is why the "FDA re-reviews" an ANDA application before granting final approval. *Id.* at 139:4-140:12. Nonetheless, she inappropriately speculates that the Generics "could have launched in 2012 because of what happened in 2015." Hamburger Decl., Ex. 25 (DeLeon Dep.) at 272:18-273:1.

C. Ms. DeLeon's Application Of Her "Experience" To The Facts Of This Case Is An Unreliable Method By Which To Reach Her Conclusions

Throughout her deposition, Ms. DeLeon confirmed that, beyond the limited record evidence that she summarizes, her opinions were based solely on her almost thirty-years of

experience in the pharmaceutical industry. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 93:22–94:14; 108:10–109:4; 158:4-5; 163:20-164:3; 260:3-8. However, Ms. DeLeon has never worked for or consulted Forest or any of the companies that launched or planned to launch generic Namenda IR (or even any generic companies of the same size), and does not have any experience with memantine products. *Id.* at. 56:17-58:4; 30:16-18; 42:7-12; 125:16-126:2 ("Q. So when you say, Such launch planning often begins approximately one year prior to the known target launch date, I'm asking when does it typically begin for memantine products? A. Well, I've never worked on a memantine product before, so I don't exactly know that one.").

Ms. DeLeon also revealed throughout her deposition that her experience yields conclusions that are divorced from the record in this case. For example, Ms. DeLeon testified that it would be "impossible" for USP method issues to delay a launch. *Id.* at 64:7-19. [redacted] She also was unaware that there were first filing generics other than the five she reviewed, and speculated that only a "very small" first-filing generic company would fail to launch. Hamburger Decl., Ex. 25 (DeLeon Dep.) at 102:5-23. ("If you want to go out on a limb and say that there were other first to filers, I guess it's within the realm if there were a very small pharmaceutical company, not these big companies like Mylan, you know, Lupin, who have resources beyond resources."). But here, Teva, the

largest supplier of generic drugs to the United States and the world, was a first filer and still failed to launch by July 15, 2015.

Ms. DeLeon's lack of experience with any of the manufacturing, equipment or capacity capabilities of the Generics, Forest or any large generic pharmaceutical company, and her lack of experience working with any memantine products, makes any conclusions regarding such companies' ability to manufacture generic Namenda that rely solely on her experience unreliable and excludable. *Trouble v. Wet Seal*, 179 F. Supp. 2d 291, 302-303 (S.D.N.Y. 2001) (excluding expert testimony because expert lacked experience in the areas of his opinion).

IV. CONCLUSION

For the foregoing reasons, under Federal Rules of Evidence 702 and 403, the Court should exclude Ms. DeLeon's opinions and testimony.

Dated: November 17, 2017

WHITE & CASE LLP

By: _____

Heather K. McDevitt
Martin M. Toto
John H. Chung
Ryan P. Johnson
William H. Bave, III
Michael E. Hamburger
Kristen O'Shaughnessy
WHITE & CASE LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200

J. Mark Gidley
Peter J. Carney
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005
Telephone: (202) 626-3600

Heather M. Burke

WHITE & CASE LLP
3000 El Camino Real
5 Palo Alto Square, 9th Floor
Palo Alto, CA 94306
Telephone: (650) 213-0300

Kevin C. Adam
WHITE & CASE LLP
75 State Street, Floor 24
Boston, MA 02109
Telephone: (617) 979-9300

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.